EXHIBIT K

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

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IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM LIABILITY LITIGATION Master File No. 2:12-MD-02327 MDL No. 2327	: :JOSEPH R. GOODWIN :U.S. DISTRICT JUDGE : :
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 2 OF MDL 200: PATRICIA LINDBERG, et al. v. ETHICON, INC., et al. Case No. 2:12-cv-01637	: : : : :

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June 3, 2016

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Oral general deposition of KONSTANTIN WALMSLEY, MD taken pursuant to notice, was held at 8 Rooney Circle, West Orange, New Jersey, beginning at 11:49 a.m., on the above date, before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

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I N D E X

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By Mr. Tomaselli 7, 125
By Mr. Orent 118

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KONSTANTIN WALMSLEY, MD,

after having been duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. TOMASELLI:

Q. Are you ready to proceed, Dr. Walmsley?

A. Yes, sir. Just logging off of my computer here.

Q. Do you want to give that a minute?

A. Certainly. Yeah.

- - -

(A discussion off the record occurred.)

- - -

BY MR. TOMASELLI:

Q. Will you please state your name for the record.

A. Konstantin Walmsley.

Q. Are you a medical doctor?

A. I am.
Q. What kind of medical doctor?
A. I'm a urologist.
Q. Okay. My name is Joe Tomaselli, and I'm here representing Ethicon. We're going to talk generally about the TVT SECUR device and other stress urinary incontinence procedures. Okay?
A. Yes.
Q. If you don't understand any of my questions, just let me know and I'll be happy to rephrase it, but if you answer, I'll assume that you understood it. Okay?
A. Okay.
Q. Are you being compensated for your time here today?
A. I am.
Q. And at what rate?
A. $500 an hour.
Q. And what did you do to prepare for your deposition today regarding the TVT SECUR?

A. Well, there's a wealth of documents and literature I've reviewed. As you know, I've provided expert reports on individuals who have undergone midurethral sling placement and had complications.

Q. Okay. And how many TVT SECUR devices have you ever implanted?

A. I have never implanted a TVT SECUR device.

Q. I'm going to mark as Deposition Exhibit Number 1 -- withdrawn.

- - -

(Deposition Exhibit No. Walmsley-1, Rule 26 Expert Report of Konstantin Walmsley, MD, was marked for identification.)

- - -

BY MR. TOMASELLI:

Q. Dr. Walmsley, I'm marking as Deposition Exhibit Number 1 your general report that was provided to me.

Can you confirm that that's what that is?

A. Yes. This is it.
Q. And that report has two general opinions in it; is that right?
A. That's correct.
Q. And general opinion number 1 relates to the instructions for use for the TVT SECUR?
A. Yes.
Q. And the last paragraph of general opinion number 1 states that it's your, Dr. Walmsley's, opinion that "the IFU for the TVT-Secur in 2010 was not sufficient to enable informed consent from the patient."
Do you see that?
A. Not in the last paragraph.
Q. I'm sorry, my bad. It's the last paragraph above the word "Adverse Reactions."
A. Yes, sir. Yes.
Q. Okay. And it is, indeed, your opinion and an opinion that you're rendering today as of 2010. Right?
A. Correct.

Q. Does the instructions for use go to the patient?
A. It's accessible to the patient.
Q. Okay.
A. But whether it goes to the patient or not, I don't believe so.
Q. And who is the IFU intended for?
A. It's intended for the clinician.
Q. The surgeon that's implanting the device?
A. Yes.
Q. Dr. Walmsley, with respect to general opinion number 1 and your statement that "the IFU for the TVT-Secur was not sufficient to enable informed consent" to "the patient, is that opinion with respect to the fact that the document alone, the IFU for the TVT SECUR alone, does not contain all the information that you think it should?
A. I'm not sure I understand

your question. I'm sorry.

Q. Okay. Is your opinion that the TVT SECUR IFU was not sufficient, is that opinion in isolation to the TVT SECUR IFU, or does it also encompass all of the training or experience that a physician might otherwise have? Did you understand my question?

MR. ORENT: Objection.

THE WITNESS: I understand your question. And I would say not specifically in isolation.

BY MR. TOMASELLI:

Q. Okay. So as part of general opinion number 1, you are considering the information that a physician implanter might bring to the table before using that device?

MR. ORENT: Objection, vague.

THE WITNESS: Well, once again, yeah, I'm trying to understand what specific information you're alluding to.

BY MR. TOMASELLI:

Q. Well, I guess what I'm asking you is, is whether your opinion is that the TVT SECUR instructions for use is not adequate just in isolation, just picking up a document and reading it. You're saying that's not enough. Or whether it is given the information that I have, even Dr. Walmsley over my career, me picking up the IFU for the TVT SECUR, it's still not adequate. Does that make sense?

MR. ORENT: Objection.

THE WITNESS: Somewhat.

BY MR. TOMASELLI:

Q. Okay. And I guess so my question is, are you really saying that the IFU itself, that, you know, without regard to other information I may or may not have, if I just picked up this piece of paper, this is insufficient by itself?

A. See, part of the difficulty in answering that question -- and you've probably seen this as well -- is that

IFUs change over time. IFUs will add or perhaps delete adverse events or precautions. So as a physician, as an implanting surgeon, we lend a certain amount of weight in terms of reading an IFU and extracting from that what is the risk/benefit analysis for this particular patient as it relates to implanting this device.

There may be information we derive at cadaveric workshops. There may be information that we derive from our partners, our colleagues, from key opinion leaders that we rely upon and trust in terms of selecting the proper patient or perhaps in the surgical technique itself. But it's all premised around the foundation of an IFU.

Q. Okay. The second general opinion that you have in your report relates to safer alternative designs and procedures existing in 2010 that have a less risk of erosion and dyspareunia with equivalent efficacy.

Do you remember that?

A. Correct.

Q. All right. And again, that opinion is as of 2010?

A. In this particular report, that's correct.

Q. All right.

A. Yes.

Q. And the safer alternative design and procedure that you list in general opinion number 2 is the autologous fascial sling using rectus fascia; is that right?

A. Yes.

Q. Okay. And in your report do you specifically list any other safer alternative design or procedure other than the autologous rectus fascia?

MR. ORENT: Objection.

THE WITNESS: The autologous rectal fascia was meant to be an example of a safer alternative design and procedure.

BY MR. TOMASELLI:

Q. And that's the only one you reference in your report. Right?

A. Correct.

Q. You go on in general opinion number 2 to say that the patient "was unable to receive proper informed consent" related "to this safer alternative because of the lack of information in the TVT-Secur IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia."

Do you see that?

A. I do.

Q. All right. Is it your opinion that the TVT SECUR IFU should have contained information regarding autologous rectal fascia and adverse events and compared the two procedures?

A. No, it's not.

Q. Okay.

A. If I could amend that sentence or perhaps make it clearer.

Q. Sure.

A. I would probably add, for

example, as an alternative to using autologous fascia. Inherent to the risks of using synthetic mesh, for example, as an alternative to using autologous fascia or some other safer alternative design and procedure.

Q. Okay. And those two general opinions, one related to the TVT IFU and secondly to the safer alternative design as set forth in your report, those are the only two general opinions that you have in this report. Right?

A. Yes, sir.

Q. Okay. In your report which is Exhibit Number 1, you list a variety of materials reviewed in connection with this report. Right?

A. Yes.

Q. And those materials are actually typed in and included in the report?

A. Yes.

Q. All right. Is there a separate document or anything that you

have that's not part of this report that has materials reviewed for this case?

A. I have a binder of reports -- pardon me -- of papers.

Q. Okay. And are those the papers that are referenced in Exhibit 1?

A. That's correct.

Q. Okay.

A. Yes.

Q. And can we agree that the materials you reviewed and listed in your report do not include any Ethicon internal memorandums or e-mails or things like that?

A. That's correct.

Q. All right. And you did not review those in connection with this report; is that right?

A. With the exception of just the instructions for use, there's no Ethicon-specific documents or internal documents that are reviewed.

Q. And it's also true that you did not review and did not put in your

materials reviewed any depositions that may have been taken of Ethicon personnel. Right?

A. Correct.

Q. I'm going to mark as Deposition Exhibit Number 2, Dr. Walmsley, your curriculum vitae. Is that what that is?

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(Deposition Exhibit No. Walmsley-2, Curriculum Vitae, was marked for identification.)

- - -

THE WITNESS: Yes, sir.

BY MR. TOMASELLI:

Q. You practice at the Urology Group of New Jersey; is that right?

A. Yes, sir.

Q. And it looks like it's a group of over 20 physicians?

A. Correct.

Q. And are they all urologists?

A. We have one urogynecologist. We have a radiation oncologist. And we

have a medical oncologist as well.

Q. How many different urologists do you practice with in your group?

A. Currently 21, give or take one or two.

Q. And do you know any of those urologists, whether they are members of the American Urological Association?

A. Yes.

Q. And are some of your partners -- and I use the term "partner" generally to speak of the people that you practice with. Okay?

A. Yes.

Q. I'm not necessarily saying they're some corporate entity. All right?

A. Correct.

Q. With respect to other of your partners, are any of them members of AUGS, that organization?

A. One of them may be.

Q. Do you assist your other

partners with surgeries if needed?

A. Yes.

Q. And will they likewise assist you if you need assistance with a particular surgery?

A. Yes.

Q. Are there doctors in your group other than you that perform stress urinary incontinence surgery?

A. Yes.

Q. Are there doctors other than you that perform prolapse surgery?

A. Yes.

Q. Do you, sir, perform prolapse surgery currently?

A. Yes.

Q. My understanding is that from 1997 to 2003, you performed a urological and general surgery residency at New York Presbyterian Hospital?

A. Yes. New York Presbyterian Hospital Cornell.

Q. Cornell?

A. Yes.

Q. And after that, from 2003 and 2004 you performed a fellowship at Columbia Presbyterian there in New York in female urology and voiding?

A. And voiding dysfunction, yes.

Q. Voiding dysfunction?

A. Yes.

Q. As part of your residency and fellowship, did you receive training with respect to surgery in the pelvic space?

A. Yes.

Q. Did you receive training on, for example, open procedures as well as laparoscopic procedures?

A. That's correct.

Q. Did you receive training on stress urinary incontinence surgical procedures?

A. Yes.

Q. And what types of surgical procedures for stress urinary incontinence were you trained on in your

residency and fellowship?

A. I performed autologous fascial slings. I performed synthetic mesh-based sling procedures, performed collagen injection procedures and also performed Burch colposuspension procedures or Burch urethral suspension procedures.

Q. Were you also trained in your residency and fellowship with respect to prolapse surgery?

A. Yes, I was.

Q. And can you describe the different prolapse surgeries that you were trained on back in the late '90s, early 2000s?

A. Yes. I performed both vaginal and abdominal reconstructive procedures. The abdominal reconstructive procedures I was trained on were sacrocolpopexies. I also performed vaginal reconstructive procedures, the majority of which were native tissue repairs, along with some that utilized

biological graft materials.

Q. With respect to your training on stress urinary incontinence procedures, were you trained on different routes of using the synthetic mesh slings, such as the transobturator route or the retropubic route?

A. The two routes that I utilized in my residency and fellowship were retropubic and suprapubic.

Q. Have you subsequently been trained on the transobturator route?

A. I learned that in my private practice, yes.

Q. And have you ever used that route for patients in your private practice?

A. Yes.

Q. In terms of the synthetic mesh that you used since 1997, would those be meshes made of polypropylene?

A. With the exception of a brief experience with the Mentor ObTape, yes.

Q. And in terms of the polypropylene meshes, do you recall which ones that you were trained on and used in your private practice?

A. In my private practice?

Q. Well, let's split that up. Let's talk about training first, how about.

A. Okay. In my training, my exposure was to TVT.

Q. Is that the retropubic route?

A. Correct.

Q. Okay.

A. And then in my private practice -- I should also say in my training I utilized a product called SPARC which was an AMS-based product that was a suprapubic approach.

In my private practice, I've utilized a variety of different synthetics, retropubic, suprapubic, transobturator, single incision. I've used TVT. I've used Bard's product, both

the AJUST and the AJUST's predecessor.

If I didn't mention Boston Scientific, I used Boston Scientific materials. I used an AMS sling and also a Coloplast sling.

Q. And since 1997, how many times do you think that you've generally implanted a polypropylene midurethral sling for the treatment of stress urinary incontinence?

A. Several hundreds. Several hundreds. Somewhere between 3- and 500, I would estimate as a guess.

Q. And would you say that you've had good success with the polypropylene midurethral slings in treating stress urinary incontinence?

MR. ORENT: Objection.

THE WITNESS: Depending upon how one defines success, yes.

BY MR. TOMASELLI:

Q. Let's talk about in terms of cure rates.

Have you had good success in

terms of cure rates with the use of polypropylene midurethral slings?

A. Fairly good.

Q. Is it true that no treatment for stress urinary incontinence is 100 percent effective?

A. I think that's true.

Q. And, indeed, whether we're talking about autologous slings or synthetic slings or any other procedure, those procedures can fail to cure stress urinary incontinence?

A. This can happen.

Q. And would you agree that the medical community of surgeons performing stress urinary incontinence surgery are aware of the possibility that surgery will not cure the stress urinary incontinence?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. Would you say that that's common knowledge?

MR. ORENT: Objection.

THE WITNESS: I would imagine so.

BY MR. TOMASELLI:

Q. Do you agree that it's impossible to predict which patients will be cured and which patients won't be cured from a stress urinary incontinence procedure?

A. I think that's possible.

Q. You think it's possible to predict?

A. I do.

Q. Have you ever implanted a midurethral sling made of polypropylene when you predicted that it would fail?

A. Not to that extent, no.

Q. Have you ever implanted a polypropylene midurethral sling when you weren't sure that it would cure their stress urinary incontinence?

MR. ORENT: Objection.

THE WITNESS: I guess the way I would answer that question is,

is to say that I have implanted synthetic midurethral slings expecting better results in certain patients and possibly not as good results in other patients.

BY MR. TOMASELLI:

Q. All right. You said that when you were trained, you were trained on the TVT Classic retropubic device?

A. That's correct.

Q. And do you recall how many times that you used that device, just approximately?

A. In my fellowship, perhaps 30 to 60 times.

Q. Have you ever used that -- sorry.

Have you ever used that device in private practice?

A. I have.

Q. And would you say that you've had success in terms of cure rates with respect to that device?

MR. ORENT: Objection.

THE WITNESS: In terms of cure rates, I've been satisfied.

BY MR. TOMASELLI:

Q. Okay. Have you ever used the TVT obturator device in your private practice?

A. I have not.

Q. In terms of the obturator route for stress urinary incontinence surgery, which devices, if you can recall, did you use?

MR. ORENT: Objection.

THE WITNESS: I've used Bard devices, specifically the -- there are two Bard devices that I've used that both are no longer on the market that I've used. There's a Boston Scientific device, an AMS device that I've used, a Coloplast device that I have used and continue to use.

BY MR. TOMASELLI:

Q. Setting aside the ObTape for a second, okay, would you say that all of the polypropylene midurethral slings that

you've used are macroporous?

MR. ORENT: Objection.

THE WITNESS: Yes. I believe so.

BY MR. TOMASELLI:

Q. And would you say that they were all lightweight?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. Do you know with respect to -- withdrawn.

My understanding is that in the last five years or so, you've -- with respect to polypropylene midurethral slings, you've used the Bard ALIGN; is that right?

A. That's correct.

Q. And you've used products from AMS?

A. That's correct.

Q. And you've used Coloplast regular length and also their mini as well?

A. Correct.
Q. Do you know whether those polypropylene midurethral slings are cut mechanically or with a laser?
A. I'm not aware.
Q. With respect to the Coloplast mini midurethral sling made of polypropylene, did you say that you still use that today or you just started using it? I can't remember.
MR. ORENT: Objection.
THE WITNESS: I've recently been trained on it.
BY MR. TOMASELLI:
Q. Okay. And prior to recently being trained on the Coloplast mini sling, did you use mini slings prior to that?
A. I did.
Q. Okay. And what types were those?
A. It was a mini sling made by Contasure, C-O-N-T-A-S-U-R-E.
Q. Thank you.

A. Uh-huh.
Q. Any others?
A. No. Just that one.
Q. Dr. Walmsley, in your residency and in your fellowship, did you ever have the occasion to see a complication from the implant of a polypropylene midurethral sling?
A. Yes.
Q. And did you have the occasion to treat those complications?
A. Well, I mean, your first question was complication, and then you just asked about complications.
Q. Well --
A. So as we sit here today, I can only really think of one complication that I specifically treated.
Q. Okay.
A. Which I think in part relates to the fact that when you're a resident or a fellow, you don't necessarily have that much follow-up with the patients you treat.

Q. What complication do you recall seeing as a resident or fellow?

A. There was a patient -- I stand corrected. I guess technically there was more than one complication, but the one complication that comes to mind was a patient in my fellowship who I treated with a TVT Classic sling that presented with severe bleeding.

Q. Okay. You stated that you also performed the Burch procedure in residency and fellowship?

A. That's correct.

Q. Did you ever have the occasion to perform the MMK procedure?

A. I did not, although I had familiarity with it. I may -- you know, I stand corrected. I may have actually performed an MMK procedure as well. It's been a long time since my residency, and I know the two procedures. For whatever reason, I'm remembering the Burch urethropexy more than the MMK, but there's a strong possibility I've done

both.

Q. With respect to the midurethral sling procedures, do those involve incisions through the vagina?

A. Yes.

Q. Do autologous fascia slings involve an incision through the vagina?

A. Yes.

Q. Do slings made of biologic graft material also involve an incision through the vagina?

A. Yes.

Q. Does the Burch procedure involve an incision through the vagina?

A. Yes.

Q. Does the MMK procedure involve an incision through the vagina?

A. Yes.

Q. Is it -- what is -- withdrawn.

What is wound dehiscence?

A. Wound dehiscence describes a process where there is an area of breakdown or opening of a closure.

Q. Closure of an incision?
A. An incisional closure, correct.
Q. And is that idea different than or synonymous with a failure to heal along an incision line?
A. I think a wound dehiscence probably falls as a subset under that category of failure to heal.
Q. Okay. And is the risk of the failure of a vaginal incision wound to heal a risk with all stress urinary incontinence procedures?
A. Theoretically, yes.
Q. And if an incision wound failed to heal, would you call that a failure of the surgery or a failure of the material or procedure used to cure the stress urinary incontinence? Do you understand my question?
MR. ORENT: Objection.
THE WITNESS: Well, I mean, there are a lot of different moving parts to the question.

BY MR. TOMASELLI:

Q. Okay. So -- well, I'll just withdraw it.

Do you agree that the medical community of surgeons performing stress urinary incontinence procedures are aware of the possibility of the complication of failure to heal at the incision line?

A. Yes.

Q. When you use the term "erosion" -- well, withdrawn.

Dr. Walmsley, there are various terms in these cases related to erosion and extrusion and exposure.

Have you heard all those different kinds of terms?

A. I have.

Q. All right. And I just want to get your understanding of how you would use those terms. So if we can start with erosion first, can you describe if somebody said "I had an erosion of a sling," what would that mean

to you?

A. That would mean to me that the material -- the sling material eroded through and into an organ or space.

Q. And would the organs that a sling of whatever material can erode into be the bladder, the rectum, the urethra and the vagina?

A. Yes. Those would be some examples of that. Yeah.

Q. Okay. And it's true that biologic grafts made of pig and autologous fascia made of rectus sheath, those can erode into other organs as well. True?

A. Very fairly.

Q. It can happen?

MR. ORENT: Objection.

THE WITNESS: I've never seen it in my clinical practice, so...

BY MR. TOMASELLI:

Q. Okay. But you've seen literature, obviously, stating that you can have erosion, for example, into the

urethra with those products?

A. There have been a couple.

Q. When did you become aware of the possibility that erosion could occur with a polypropylene midurethral sling?

A. Well, fairly soon after I started utilizing the material.

Q. So you became aware of the potential for erosion for a polypropylene midurethral sling dating back to the late '90s?

MR. ORENT: Objection.

THE WITNESS: Once again, in the late '90s, I was early in my residency. And I didn't -- you know, as a resident, I was really more involved in the operative side of things than I was in patient follow-up.

BY MR. TOMASELLI:

Q. Okay. In terms of the timing, then, would you say that you were certainly aware of the possibility that erosion or exposure could occur with a

polypropylene midurethral sling by the early 2000s?

MR. ORENT: Objection.

THE WITNESS: I would say that by 2004 I was aware of that.

BY MR. TOMASELLI:

Q. Okay. And how did you become aware of the possibility that erosion or exposure could occur with a midurethral sling made of polypropylene?

A. Well, two reasons. I mean, one was in my fellowship and early private practice going to workshops where erosion was discussed. And secondly, in terms of reading the IFUs at that time that talked about erosion in a particular context.

Q. And when you say that you went to workshops and that was discussed, can you describe what kind of workshops those are?

A. Yes. I went to several different cadaveric training workshops where there would be didactic sessions

and then labs where you'd operate either -- mostly on human cadavers implanting mesh.

And during those conferences, if you will, there were discussions about erosion.

Q. Were you also aware of reports, for example, in the medical literature that discussed erosion or exposure of polypropylene midurethral slings into other organs?

MR. ORENT: Objection.

THE WITNESS: I did have awareness of that.

BY MR. TOMASELLI:

Q. When did you become aware of the possibility that scarring in the vagina could occur with a surgery for stress urinary incontinence?

A. Well, I mean, scarring is a natural phenomenon from any surgery. Whether it's surgery for stress urinary incontinence or removing a kidney tumor, I mean, scarring is the natural process

of healing.

Q. Okay. When did you become aware of the possibility of pelvic pain or groin pain or suprapubic pain with the use of midurethral slings for stress urinary incontinence?

MR. ORENT: Objection.

THE WITNESS: Well, I think I'd have to probably answer that question the same as the first. It's -- those terms, "pelvic pain," "groin pain," those are natural phenomena from a sling procedure, whether it's done -- you know, whatever the material is that's used.

BY MR. TOMASELLI:

Q. Would you say the same for the possibility of bleeding or infection or a wound complication?

A. I would.

Q. I want to talk to you for a second about dyspareunia, which is pain with intercourse. Right?

A. Yeah.

Q. Are there other courses of dyspareunia other than a stress urinary incontinence procedure?
A. Yes.
Q. Would one of those be vaginal atrophy or atrophic vaginitis?
A. That's one, yes.
Q. What are some others?
A. Prior pelvic surgery, radiation to the pelvis, inflammatory conditions affecting the vulva or the vagina.
Q. When you say "prior pelvic surgery," what's in your mind when you say that? Sorry for my legs.
A. Oh, hysterectomy. Any sort of pelvic surgery that creates fibrosis or scarring as part of its healing process.
Q. Would you agree that new onset dyspareunia is a risk, a potential risk, with all stress urinary incontinence procedures?
MR. ORENT: Objection.

THE WITNESS: With the exception of collagen injection, there's some truth to that.

BY MR. TOMASELLI:

Q. Okay. So let's set collagen injection to the side for a second.

Would you agree that new onset dyspareunia is a risk with all stress urinary incontinence surgeries?

MR. ORENT: Objection. I don't know that you can actually just cherry-pick out to get your quote one of the surgeries. I think his answer is no. And then he answered what surgery you couldn't. And now you're asking him aside from the surgery that can't, are there any surgeries that can. So I don't think that's a proper question.

MR. TOMASELLI: All right. Let me start over. And, you know, you can say objection, form, and that will be just fine.

BY MR. TOMASELLI:

Q. Let me start over. Sorry if I was unclear, Doctor.

Dr. Walmsley, would you agree that new onset dyspareunia is a risk with all midurethral sling procedures using polypropylene mesh?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. Would you agree that new onset dyspareunia is a risk with autologous fascia procedures for stress urinary incontinence?

MR. ORENT: Objection.

THE WITNESS: To some degree, yes.

BY MR. TOMASELLI:

Q. And would you provide the same answer with respect to the biologic grafts used for stress urinary incontinence procedures?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. And would you provide the same answer with respect to the Burch procedure?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. Is it also a possibility, Dr. Walmsley, that dyspareunia that a patient suffers before a procedure for stress urinary incontinence can actually resolve or get better after the procedure?

MR. ORENT: Objection.

THE WITNESS: I've not seen that before. It depends, obviously, on what the cause of the dyspareunia is pre-procedure. So if there's some sort of concurrent treatment of the cause of the dyspareunia, I suppose that's possible. For example, a cystocele might cause dyspareunia. And if one fixes the cystocele, that might fix the cystocele-induced

element of the dyspareunia, for example.

BY MR. TOMASELLI:

Q. Thank you. Are urge incontinence and overactive bladder symptoms -- well, withdrawn.

Can a woman suffer urge incontinence and overactive bladder symptoms in the absence of undergoing a surgical procedure for stress urinary incontinence?

A. Yes.

Q. All right. Is there a background rate of overactive bladder symptoms in women?

A. Background rate? I don't understand that terminology.

Q. Sure. So in your practice, I suppose that you have a general female urology practice?

A. I do.

Q. And are there women that come to you that have overactive bladder symptoms that have never had a stress

urinary incontinence procedure?

A. Yes.

Q. If a woman came to you with overactive bladder symptoms, is that a common thing that you see in your practice, or is that relatively uncommon?

MR. ORENT: Objection.

THE WITNESS: Fairly common.

BY MR. TOMASELLI:

Q. And with respect to urge incontinence, I assume you see that in your practice?

A. I do.

Q. And can urge incontinence occur, again, in the absence of having a stress urinary incontinence procedure?

A. Yes.

Q. Is it also possible that a woman without urge incontinence can have a new onset of urge incontinence after a surgery for stress urinary incontinence?

A. That can happen.

Q. Can that happen, that is, new onset urge incontinence, can that

happen with any polypropylene midurethral sling surgery?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. Can it occur also with surgeries using autologous fascia or biologic grafts?

MR. ORENT: Objection.

THE WITNESS: To some degree, yes.

BY MR. TOMASELLI:

Q. Can new onset urge incontinence also occur with the Burch procedure?

MR. ORENT: Objection.

THE WITNESS: To some degree, yes.

BY MR. TOMASELLI:

Q. What is urinary retention?

A. That is an inability to void, where your bladder becomes overextended.

Q. Okay. And can urinary

retention occur in women in the absence of a stress urinary incontinence surgery?

A. Yes.

Q. You see that in your practice?

A. I do.

Q. And can urinary retention also be associated with any stress urinary incontinence surgery?

A. Yes.

Q. Can urinary retention be associated, again, with procedures utilizing autologous fascia, for example?

A. Yes.

Q. Is there a way to predict with women undergoing a procedure for stress urinary incontinence who or who will not potentially have a complication of urinary retention after that surgery?

A. To some extent, yes.

Q. And what do you think about in terms of -- in that regard?

A. I think about patients who are on medications that might otherwise

relax their bladder, for example, antidepressants. I think about patients who have stress urinary incontinence in the setting of incomplete bladder emptying or a somewhat weakened bladder. Those are a couple of instances where I point out to a patient that she might have a higher risk of retention following surgery.

Q. Okay. When would you say, Dr. Walmsley, that you became aware of the potential for urge incontinence or overactive bladder symptoms or urinary retention? When would you say that you became aware of those potential complications with stress urinary incontinence surgery?

A. Fairly early in my experience with them.

Q. So would that be -- again, pegging your fellowship being in the early 2000s, would that be a reasonable time?

MR. ORENT: Objection.

THE WITNESS: I think that's reasonable.

BY MR. TOMASELLI:

Q. Dr. Walmsley, do you have any peer-reviewed publications regarding prolapse or stress urinary incontinence surgery?

A. I have given grand rounds on the management of both medical and surgical for urinary incontinence, if that answers your question.

Q. Okay. Let's break those up real quick if we can.

A. Sure.

Q. Dr. Walmsley, do you have any peer-reviewed publications pertaining to the management of prolapse or stress urinary incontinence?

A. I don't.

Q. Do you have any peer-reviewed publications pertaining to the use of mesh with prolapse or with stress urinary incontinence surgery?

A. I don't.

Q. Dr. Walmsley, have you ever performed grand rounds with respect to the management of stress urinary incontinence?

A. I have.

Q. And when would you say that you've done that?

A. I did that in 2006.

Q. Is that the one that you did at the Mountainside Hospital?

A. That's correct.

Q. All right. Would it be -- withdrawn.

Do you have any materials or did you provide any materials at the time of that grand rounds, like a presentation or handouts or anything?

A. I had a PowerPoint presentation.

Q. Do you think that you still have that PowerPoint presentation?

A. Highly possible, yes.

Q. If -- let me ask you this question: If you had that PowerPoint

presentation, where do you think you might have kept it or do keep it?

MR. ORENT: Objection.

THE WITNESS: I may have it in one of my computers, yeah.

If I have a memory stick of it, I -- that's another possibility, although I don't know where the memory stick is right now.

BY MR. TOMASELLI:

Q. Okay. Other than the grand rounds in 2006 at Mountainside Hospital, have you ever made any other public presentations regarding the management of stress urinary incontinence?

A. I've lectured to students. Actually, correct that. I'm sorry. I've lectured to residents, family practice and internal medicine residents on topics of this nature.

Q. Sorry. Where were those residents engaged?

A. They were Mountainside Hospital as well.

Q. Is that something you do -- try to do often or --

A. I enjoy teaching, so I do.

Q. Do you think that's something you've done recently?

A. Probably in the last several years, yes.

Q. And when you do that, when you lecture to the residents, do you have a set of materials, or is that more just you talking?

A. It's usually a PowerPoint presentation.

Q. And do you think that if you looked around, that you might be able to find those presentations?

MR. ORENT: Objection.

THE WITNESS: Highly possible. Highly likely, yeah.

BY MR. TOMASELLI:

Q. My understanding is that you're the Hackensack chief of the department of surgery?

A. That's correct. Well, it

should say Hackensack UMC Mountainside. It's one of the satellite hospitals of Hackensack.

So there's a Hackensack University Medical Center in Hackensack that has its own chairman of surgery. I'm the chairman of surgery at HUMC Mountainside as it's called.

Q. Okay. Thank you for that clarification.

And where is that hospital?

A. It's in Montclair, New Jersey.

Q. Is it true that the department of surgery at Hackensack provides the highest quality clinical and surgical care to its patients or it attempts to?

A. I think it aspires to, yes.

Q. And does the hospital buy the surgical devices related to urologic surgeries in the hospital?

MR. ORENT: Objection.

THE WITNESS: It does.

BY MR. TOMASELLI:

Q. It does?

A. Yes.

Q. And do you know what devices for stress urinary incontinence surgery that they stock for their physicians?

A. Yes.

Q. Okay. And in terms of midurethral slings made of polypropylene, do you know which ones they stock?

A. Yes.

Q. And which ones are those?

A. Coloplast. And there may be some -- may be some Boston Scientific slings on -- as well.

Q. Any others?

A. I don't believe so today, but I'm not 100 percent sure. I'm not -- you know, I'm not in central sterile supply checking, but...

Q. Understand. But safe to say the HUMC Mountainside Hospital does stock midurethral slings for the treatment of stress urinary incontinence that are made

of polypropylene?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. Have you ever done any consulting for a pharmaceutical or medical device company?

A. I have not.

Q. In your general opinion number 1, Dr. Walmsley, you state that "before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure...the surgeon must be informed on the risks/benefits/alternatives."

Do you see that?

A. I do.

Q. When we speak of stress urinary incontinence surgery, what are the different ways that a surgeon can inform themselves on the risks, benefits and alternatives of that?

MR. ORENT: Objection.

THE WITNESS: Well, certainly one is through a review of

the IFU, the instructions for use.
The other may come in the form of the experience one has had during their training, during their residency and fellowship.
From my standpoint, having come out of my training in 2004, some of my experience came with going to training workshops that we discussed, involving didactic and cadaveric workshops and such.
And lastly, some of it is based on clinical experience one has in his or her private practice or academic practice, as the case may be.

BY MR. TOMASELLI:

Q. Could physicians also gain that information through conversations with their colleagues in practice?

A. I think those can be helpful, depending upon the colleague.

Q. I won't tell anybody.
Would some of that information that surgeons can get come

from, for example, the medical literature?

A. Yes.

Q. Would some of that information, might it come also from pronouncements or writings from the FDA?

MR. ORENT: Objection.

THE WITNESS: Not often, but it can happen.

BY MR. TOMASELLI:

Q. Would some of that information possibly come from recommendations or practice guidelines from national organizations?

MR. ORENT: Objection.

THE WITNESS: To some degree, yes.

BY MR. TOMASELLI:

Q. Would some of that information also come from potentially attending national meetings, for example, of the Urological Association?

MR. ORENT: Objection.

THE WITNESS: Yes.

BY MR. TOMASELLI:

Q. Because there are presentations and posters and abstracts and lectures and things like that?

A. Yes.

Q. And would you say that you have accumulated knowledge over your career about stress urinary incontinence procedures and their outcomes and complications, that you've gained experience over the years?

A. This is true.

Q. Would you also say that you've accumulated knowledge over the years about when and what patients those procedures might be more likely to fail or might be more likely to be associated with a complication?

A. Yes.

Q. In performing surgery on your patients for stress urinary incontinence, would you consider and draw or try to draw from all the experience that you've gained over the years from

those variety of sources of information?

A. Yes.

Q. And would you expect that -- each surgeon to do the same, that is, to draw from the information and the experience that they've been exposed to?

A. I would imagine that would be reasonable.

Q. Do you, Dr. Walmsley, hold yourself out as an engineer of any type?

A. No.

Q. Do you hold yourself out as an anesthesiologist?

A. No.

Q. Do you hold yourself out as a pain specialist?

A. Not in the sense of a pain specialist under the anesthesia umbrella, no.

Q. Have you ever drafted a label for a medical device or a medication?

A. I have not.

Q. Have you ever consulted with

a company regarding language, whether it should be in or not in a particular label?

A. Not that I can recollect, no.

Q. Makes sense since you haven't consulted with medical device or pharmaceutical companies?

MR. ORENT: Objection.

THE WITNESS: I've not, but I've been involved in the marketing end of things, where companies will come and show me different schemas and advertisements for different products, and I'll give feedback as to what I think is perhaps more conducive or relevant to what a physician wants to see and things of that nature.

BY MR. TOMASELLI:

Q. And do you recall which products that you've done that with?

A. Well, there have not been -- to my recollection, they've not been medical device products, they've mostly

been medications.

Q. Are those for overactive bladder?

A. Some of them, yeah.

Q. Outside of litigation, have you ever communicated to a company that their labeling -- to a medical device company that their labeling was inadequate?

A. Labeling regarding what exactly?

Q. A medical device used for stress urinary incontinence.

A. I've never given any advice regarding labeling for an SUI product outside of litigation.

Q. Have you ever read the FDA regulations pertaining to the labeling of medical devices?

A. Indirectly I have.

Q. And when you say indirectly, what do you mean by that?

A. Well, when I first became involved in some of the litigation that

you and I are involved with today, I did review some of that. I mean, scratching the surface type of stuff.

Q. Let's -- prior to becoming retained in litigation, did you ever have the occasion to go and read the FDA regulations pertaining to medical devices?

A. No.

Q. Have you ever worked or been employed by the FDA?

A. I've not.

Q. Have you ever been asked by the FDA to consult with respect to any aspect of a medical device?

A. No.

Q. You said in your report that you were trained on the TVT device.

Were you referring to that being in your residency and fellowship?

A. Primarily my fellowship and a little bit of residency. More exposure in fellowship.

- - -

(A recess was taken from 12:50 p.m. to 1:06 p.m.)

- - -

BY MR. TOMASELLI:

Q. Dr. Walmsley, we took a short break, and before that, we were talking about your training with respect to the TVT device.

Do you remember that?

A. Yes, sir.

Q. I'm marking as Deposition Exhibit Number 3 a surgeon's resource monograph related to the TVT device.

- - -

(Deposition Exhibit No. Walmsley-3, Surgeon's Resource Monograph, Bates stamped ETH.MESH.10027307 through ETH.MESH.10027328, was marked for identification.)

- - -

BY MR. TOMASELLI:

Q. Do you see that?

A. I do.

Q. Do you remember ever receiving this document?
A. I have seen this in past.
Q. All right. And with respect to yourself or other surgeons who saw it, would you agree that the information contained in it could then be incorporated into a, you know, risk/benefit idea pertaining to the TVT device itself?
MR. ORENT: Objection.
THE WITNESS: You mean for those that have seen this?
BY MR. TOMASELLI:
Q. Yes, sir.
A. It could be helpful.
Q. Again, they could read it, and that information could be incorporated into their thinking?
A. Yes.
Q. All right. And to be clear, Dr. Walmsley, the TVT SECUR midurethral sling is made of Prolene, which is the same material that the TVT retropubic

device is made from, and that's your understanding. Right?

MR. ORENT: Objection.

THE WITNESS: That's a polypropylene device.

BY MR. TOMASELLI:

Q. Yes, sir.

A. Yes.

Q. And it uses the trade name Prolene, polypropylene mesh, in both the TVT retropubic device that's talked about in this document as well as the TVT SECUR?

MR. ORENT: Objection.

THE WITNESS: Correct.

BY MR. TOMASELLI:

Q. Your general opinion number 1 again relates to the information contained in the IFU for the TVT SECUR as of 2010. Right?

A. Right.

Q. Okay. My understanding is that the basis for your opinions in general opinion number 1 come from,

number one, the fact that you read the TVT SECUR IFU?

A. Correct.

Q. I think you also reference your experience in this section. If you go down to the bottom of this page, "In my experience" with "dealing."

A. That speaks to talking about mesh-induced foreign body response.

Q. Okay. But in terms of your opinion regarding general opinion number 1, your experience plays into your opinions? I'm asking if that's part of your basis.

A. Could you repeat your question? I'm not clear as to the nature of it.

Q. So let me back up.

A. Uh-huh.

Q. General opinion number 1 states that it's your opinion that the IFU for the TVT SECUR in 2010 was not sufficient to enable informed consent?

A. That's correct.

Q. Okay. That's based upon, number one, your reading of the TVT IFU?

A. That's based solely on my reading of the TVT IFU, yes.

Q. Okay.

A. Yeah.

Q. No other basis for that opinion?

MR. ORENT: Objection.

THE WITNESS: Well, I mean, I think to some degree the basis of that opinion comes -- is borne out of the fact of the complications and adverse events that do occur, they aren't specifically spoken towards in the IFU. So when you asked me, for example, when I said "in my experience," that supports my opinion regarding the insufficiency of the TVT SECUR IFU.

BY MR. TOMASELLI:

Q. You also reference a medical dictionary pertaining to the words "transitory" and "transient"?

A. Correct.

Q. All right. So in terms of the IFU label, your experience that you are drawing from in evaluating that and the medical dictionary for the terms "transient" and "transitory," are there other bases for your opinion that you came to in general opinion number 1?

A. Not specifically, no.

Q. In general opinion number 1, you take issue, obviously, with the word "transient" and "transitory" that are in the TVT SECUR IFU. Right?

A. That's correct.

- - -

(Deposition Exhibit No. Walmsley-4, Gynecare TFT SECUR System IFU, Bates stamped ETH.MESH.02340568 through ETH.MESH.02340590, was marked for identification.)

- - -

BY MR. TOMASELLI:

Q. And Exhibit 4 is the IFU for

the TVT SECUR. Right?

A. Yes.

Q. Is there anything else in this IFU that you do not think is accurately set forth? I know you have opinions regarding omissions, and we'll get there. But in terms of things that are not accurately set forth, like the word "transient" or "transitory," are there other things?

A. With the exception of what I've talked about in adverse reactions in my general opinion, there really is nothing else here that I'm critical of.

Q. Okay. In your general opinion number 1, you state that the -- well, withdrawn.

With respect to your last answer, that you -- that there's nothing else that you're critical of, in terms of the adverse reactions, you're critical of the fact that they -- that it talks about transitory local irritation and a transitory foreign-body response. Right?

A. That's right.
Q. Otherwise, the adverse reactions are accurate, in your mind?
A. No.
Q. They're not?
A. No. That's not correct.
Q. Okay. Why are they not accurate?
A. In large part, because there are several additional potential adverse reactions that I believe I elucidate in the following page.
Q. Right. And I'm going to come to the things that you think should also be in there.
A. Okay.
Q. I guess what I was getting toward was you take issue with the accuracy of the words "transitory" --
A. Correct.
Q. -- and "transient." Right?
A. Right.
Q. Is there anything else that you take issue with the accuracy of?

A. As far as the five adverse reactions listed in the IFU?

Q. Yes, sir.

A. Well, I mean, I think that the first one, which is "Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during instrument passage and may require surgical repair," that to me is an appropriately stated adverse reaction.

The second one, obviously I take issue with the term "transitory," because typically the foreign-body response is certainly neither transient nor transitory.

And the second concern I have regarding that particular bullet point is the lack of context relating to extrusion, erosion, fistula formation or inflammation as it relates to treatment.

I mean, for example, in this document, there's actually a lot more language about what a surgeon in the trenches might need to do to handle that,

whereas in the IFU here it's really not elaborated on.

Q. And when you talk about that these items in the IFU are elaborated in a different document, you were holding up --

A. I was holding up the --

Q. Exhibit Number 3, the Surgeon's Resource Monograph?

A. Correct. Right.

Q. Again, anything else that you say is actually not accurate in these statements?

A. No.

Q. All right. With respect to the next page, you state that the IFU does not include the words, for example, "mesh contraction" or "mesh shrinkage." Correct?

A. Correct.

Q. And it's your opinion they should have?

A. That's correct.

Q. All right. And in terms of

the clinical consequences of the mesh contracting or the mesh shrinking, would that include things like pain with intercourse?

A. That could be one, yes.

Q. Would it include things like pelvic pain?

A. That's correct.

Q. Would those be the most common clinical consequences of mesh contraction or mesh shrinkage?

A. Not completely, but some of them.

Q. Can you identify other clinical consequences that you would identify with that?

A. Yes.

Q. Sure. Go ahead.

A. Voiding dysfunction. Vaginal shortening. Kind of -- scar-plate formation, which is kind of a part of -- to some degree part of mesh contraction, but is related to that in certain instances.

Q. And in terms of scar-plate formation, what's the clinical consequence of -- what does a patient feel from scar-plate formation?

A. Well, it depends on, for example, if they're sexually active, they'll feel it more. Sometimes they'll feel it simply from the standpoint of having pain related to that phenomenon. But the important reality to keep in mind is that the vagina is a dynamic organ. There are studies that demonstrate that vaginal length can expand by up to 50 percent or more during stimulation, for example. And the presence of scar-plate formation, particularly if there is a mesh response involved, an untoward mesh response, that that can exacerbate that problem.

Q. And would that -- would what you just described in the last answer, would that apply to all midurethral slings made of polypropylene mesh?

MR. ORENT: Objection.

THE WITNESS: Well, possibly, yeah.

BY MR. TOMASELLI:

Q. Could it also possibly apply to biologic graft material?

A. Much less so.

Q. But it could possibly?

A. Theoretically.

Q. You state that the IFU does not warn about the difficulty of removing mesh; is that right?

A. That's correct.

Q. Do you agree that the design of the midurethral sling with polypropylene mesh is such that that mesh will incorporate into the surrounding tissue?

A. It's meant to.

Q. Is that also the same with respect to autologous fascia and biologic grafts, that you expect those materials to incorporate into the surrounding tissue?

A. In a different fashion, but

yes.

Q. Are any of the devices, a midurethral sling made of polypropylene, a biologic graft, an autologous fascia or other devices, are they meant to be permanent?

A. They're intended to be, yeah.

Q. Is it true that surgeons operating in this space and using those devices understand that they're permanent devices?

A. Yeah, I believe so. Yes.

Q. I think you also state in your general opinion number 1 that the IFU does not warn of dyspareunia. Right?

A. That's correct.

Q. And you think it should?

A. I do.

Q. All right. And we talked a little bit about dyspareunia before. Right?

A. Yes.

Q. And is it true, again, that

dyspareunia can actually pre-exist a surgery, a stress urinary incontinence surgery?

A. True.

Q. And it's true that dyspareunia can come about or be new after a stress urinary incontinence surgery?

A. True.

Q. And I suppose the other possibilities are that pre-existing dyspareunia could get worse, or, as you mentioned, the possibility of it getting better?

MR. ORENT: Objection to form.

BY MR. TOMASELLI:

Q. Possibly?

A. Yeah. All true.

Q. And would you say the same thing for, for example, pelvic pain, that, again, it could pre-exist or become new after a stress urinary incontinence surgery?

A. True.
Q. If you could turn to Exhibit 4. I think you're with me.
A. Uh-huh.
Q. Do you see where there's a page about warnings and precautions? It might be one back or so from where you are.
A. I do.
Q. Maybe a couple back.
Do you see that?
A. I do.
Q. All right. Do you see the third bullet where it says, "Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT SECUR System before using"?
A. I do.
Q. And when you read that users should be familiar with urethral suspension surgical techniques, what does that mean to you as a surgeon?
A. What that means is that if

I'm coming into this space, interested in using, let's say, the TVT SECUR product, I should do so having a foundation of knowledge having performed other urethral suspension surgeries before embarking on training in these procedures.

Q. When you talk about the surgeries themselves, what types of surgeries are you thinking about?

MR. ORENT: Objection.

THE WITNESS: Well, I mean, I don't know. It's a fairly general comment. Surgical technique for urethral suspensions, I mean, that could include Burch, MMK procedures. That could include prior midurethral sling procedures. So it's a bit of a generic statement, to be fair.

BY MR. TOMASELLI:

Q. Sure. And could it -- I mean, if you read that, could you also -- that could include autologous fascia or biologic grafts as well?

A. It could.

Q. And when it says -- well, withdrawn.

And when it says that you should -- users should be familiar with these, again, how does a surgeon become familiar with those procedures such as the Burch, the MMK, autologous fascia? Can you describe how a surgeon would become familiar with those?

A. Well, I mean, I can describe how I became familiar with them.

Q. Okay.

A. And that was through my training, through training in which I was an apprentice/resident, seeing my attendings perform these procedures, getting involved with them as an assistant and then finally kind of executing them with my attendings supervising me.

Q. And would you also, again, gain information -- I guess in those various things we talked about earlier, would you gain information about those

surgical procedures in the same way?

A. I think to some degree, yes.

Q. Okay. By the way, who was your -- who did you train under as a fellow?

A. In my residency -- in my fellowship I was under a gentleman named Steven Kaplan.

Q. Is that with a K?

A. Yeah, K-A-P-L-A-N, Steven.

Q. And who did you train under as a resident in urologic surgery?

A. My residency with regards to female urology, slings and such, I trained under a gentleman named George Young, Jerry Blaivas, and David Staskin, S-T-A-S-K-I-N. And Blaivas is B-L-A-I-V-A-S, or V-I-S or A-S.

Q. Did you find that all those surgeons were well informed and good at what they did?

A. I felt like they were.

Q. Would you say that you learned a lot from them?

A. A lot, yes.

Q. When we talk about general opinion number 2 in your report, that's the one that references the autologous fascia as a safer alternative design in 2010 to the TVT SECUR.

Do you remember that?

A. Correct.

Q. In the first sentence, Dr. Walmsley, you state that these designs and procedures existed in 2010 that have a less risk of erosion and dyspareunia, which I'll get to, but you also say that they have substantially equivalent efficacy.

Do you see that?

A. Correct, yes.

Q. Okay. Are you saying there that, for example, the autologous fascial sling has equivalent efficacy in terms of curing stress urinary incontinence, are you saying it has equivalent efficacy to the TVT SECUR?

A. In this document, yes.

Q. Okay. And is that your opinion, that the TVT SECUR had equivalent efficacy, for example, to the autologous fascial sling?

A. I think it's a little bit of an apples to oranges comparison in part because there's a richer or more prevalent amount of literature for the autologous slings compared to the TVT SECUR, because the TVT SECUR was really only on the market for only a brief period of time, so...

And the follow-up on a lot of the studies for TVT SECUR were somewhat short comparatively to the autologous fascial sling. But generally speaking, I would hold that to be true.

Q. Did you go and try to search for all the TVT SECUR literature from, say, 2005 up to 2010 and see what there was out there?

A. I've looked at some of that literature.

Q. All right. There are, in

fact, studies that are published regarding the TVT SECUR prior to 2010 that have outcomes up to a year or more?

A. I thought I --

MR. ORENT: Objection.

THE WITNESS: I thought I saw a year, 18 months.

BY MR. TOMASELLI:

Q. Okay.

A. But to be fair, there are also autologous fascial slings that have five, five-year data and so forth.

Q. In terms of the -- maybe the one-year outcomes, is that more apples to apples?

A. Yeah. We can compare one year/one year for each.

Q. When you say that the autologous fascial sling had substantially equivalent efficacy, would you say that maybe at the year point, the autologous fascial sling had substantially equivalent efficacy to the TVT SECUR?

MR. ORENT: Objection.
THE WITNESS: I would say that.
BY MR. TOMASELLI:
Q. Is that a yes?
A. I would say yes.
Q. In your general opinion number 2, you say that the autologous fascial sling has a less risk of erosion than the TVT SECUR.
What's your basis for that statement?
A. My clinical experience and the literature surrounding TVT SECUR compared to autologous fascial slings.
Q. When you reference the literature surrounding autologous slings and the TVT SECUR, are you referencing studies that have them head to head or the general body of literature for both?
A. The latter. I don't know of any head-to-head studies comparing the two myself.
Q. That was my next question.

A. Yeah.
Q. Dr. Walmsley, maybe we'll get that one out.
A. Right.
Q. Withdrawn.
Dr. Walmsley, are you aware of any head-to-head studies between the TVT SECUR and the autologous fascial sling using rectus fascia?
A. I'm not.
Q. When you say in your general opinion number 2, Dr. Walmsley, that the TVT SECUR has a higher rate of dyspareunia than the autologous fascial sling using rectus fascia, what's the basis for your opinion?
A. Once again, a review of the literature that gives dyspareunia rates for each of those techniques, and to some degree, although I've never had clinical experience with TVT SECUR implanting it, I've seen patients implanted with TVT SECUR that have had complaints of dyspareunia.

Q. And what would you approximate the rate of dyspareunia for the TVT SECUR as opposed to the rate of dyspareunia for the autologous fascial sling based on the literature? Do you have numbers in mind? That's my question.

A. Yeah. I mean, I think based on autologous fascial sling, you're talking maybe 1 to 3 percent, whereas for TVT SECUR you're looking at somewhere in the high single digits. But I mean, think, once again, to be -- to give a completely thorough answer, one has to really talk about the nature of the dyspareunia. I mean, not all dyspareunia is created equal. And certainly in my clinical experience, and the literature would speak to this, perhaps not specifically for TVT SECUR, but perhaps it's a different kind of dyspareunia.

Q. And the different kind of dyspareunia that you're referencing, would that also apply to other

midurethral slings made of polypropylene mesh?

A. To some degree, yes.

Q. When you say to some degree, what do you mean?

A. Well, once again, I think when you're looking at literature or peer-reviewed journals that talk about dyspareunia, it's sometimes one's definition of dyspareunia can be different. Sometimes the questions aren't asked, do you have dyspareunia, for example. So I think to really give a hard and fast objective, let's say, number, it's a bit misleading.

What I can tell you in my clinical experience is that if I've encountered dyspareunia in an autologous fascial sling, which is exceedingly rare, it tends to be something that's mild, something that can be treatable, for example, with vaginal estrogen, where in the TVT SECUR setting, I have encountered a handful of patients, less than five,

but memorable patients, where the scarring and healing process inherent to that device, you know, not only renders them with dyspareunia but the kind of pain that you can reproduce on an exam where you're feeling -- we call it indurated tissue, but heavily scarred-in tissue that's undergone a very intense response to the implant.

So that's why I think you can say a percentage number, but I don't think the percentage number necessarily gives a full meaning.

Q. All right. So if I understand your opinion in general opinion number 2 is that the lesser risk of erosion with an autologous sling you would say is both lower in terms -- withdrawn. Let me try this again.

Dr. Walmsley, if I understand your opinion in general opinion number 2 regarding dyspareunia, it's that when you compare the TVT SECUR to the autologous fascia, there's not

only a numerical less risk with dyspareunia, but the dyspareunia is of a different character?

A. Correct.

Q. In terms of the less risk of erosion between the TVT SECUR and the autologous fascia, where are you discussing the erosion, by the way? Is that erosion into any organ?

A. Yeah. That would fall under that category.

Q. And in terms of, again, putting -- if you put a number on the less risk that you believe is with an autologous sling compared to the TVT SECUR, can you try to do that based on your review of the literature?

A. I can.

Q. Can you do that?

A. The most recent Cochrane analysis -- this is a reliance list or a piece of information that I've recently reviewed that is not in this particular document -- the rate was about 12 percent

with synthetics, TVT SECUR falling under that category; whereas for autologous, it's in the order of 1 to 2 percent.

Q. And when you reference this Cochrane analysis, do you recall the first author of that? Is that Ford?

A. It's either Ford or --

Q. Oga?

A. Ott maybe. I have it in my computer, but I don't remember specifically who it is. But it's a 2016 Cochrane review report.

Q. Are there adverse events in that Cochrane report that are more common with autologous slings than with TVT midurethral slings?

A. Once again, this wasn't a comparison of the two. This was looking at -- that 12 percent is off that Cochrane review. The 2 percent is more of an amalgamation of my readings of other autologous fascial sling reviews. So they aren't comparing one and the other, to be fair.

Q. Okay. And I think we established this, but you're not aware of any randomized clinical trial comparing an autologous rectal fascial sling to the TVT SECUR?

A. I'm not.

Q. And you're not aware of any observational study, whether prospective or retrospective, comparing the autologous fascial slings to the TVT SECUR?

A. I'm not.

Q. Based on your review of the literature, would you say that there are any complications with respect to the autologous rectal fascial slings that are more common than you would otherwise see in a TVT midurethral sling?

A. There are a couple.

Q. Can you describe those for me?

A. One is the fact that you're harvesting fascia, so you're making an additional incision. I don't know if

that's an adverse event or a complication, but as a result of that, there is temporarily at least more pain related to that.

Q. Would you agree that urinary retention is higher with respect to autologous fascial slings than with the TVT midurethral sling?

A. That can happen, yes.

Q. Would you agree there are more wound complications, maybe because of the harvesting, with respect to autologous fascial slings than the TVT devices?

A. That's a temporary phenomenon that can occur, yes.

Q. Dr. Walmsley, in your expert report that contains your materials reviewed list, there are a series of articles that you cite. Correct?

A. Yes.

Q. The first article I've marked as Exhibit Number 5.

- - -

(Deposition Exhibit No. Walmsley-5, Article entitled "A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in the treatment of genuine stress incontinence" by Hilton, was marked for identification.)

- - -

BY MR. TOMASELLI:

Q. Which is a paper by Hilton. Do you see that?

A. I do, yep.

Q. And I don't know if you know this off the top of your head.

MR. ORENT: Can I get a copy of that?

MR. TOMASELLI: You may. So withdrawn. I'll start a new question.

MR. ORENT: Thank you.

BY MR. TOMASELLI:

Q. Exhibit 5 is, indeed, the Hilton paper. Correct?

A. Yes.
Q. And do you recall why you cited this paper in connection with your report?
A. Well, the -- to get an idea of a comparison between a sling and this endoscopic technique, which really, quite frankly, doesn't occur much anymore. That was the main intention.
Q. And the sling that was used in this study was actually made of pig graft?
A. Correct, yes.
Q. And if you turn to Table 6 of the paper on page 216 --
A. Uh-huh.
Q. -- there are a list of complications; is that correct?
A. Yes.
Q. And so would you agree that, again, physicians like yourself who are reviewing these papers can look at the operative and postoperative complications, and it helps inform their

view as to what can possibly happen during a stress urinary incontinence surgery?

A. Yes.

- - -

(Deposition Exhibit No. Walmsley-6, Article entitled "Comparison of Burch and Lyodura Sling Procedures for Repair of Unsuccessful Incontinence Surgery," by Enzelsberger, et al., was marked for identification.)

- - -

BY MR. TOMASELLI:

Q. Dr. Walmsley, I'm going to hand you what I've marked as Deposition Exhibit Number 6, which is a paper by Enzelsberger from 1996.

Do you see that?

A. I do.

Q. And this is the second paper in your materials reviews list?

A. Yes.

Q. And do you recall why you

decided to cite this particular paper in your report?

A. I thought it would be helpful to have a comparison, maybe apples to oranges because of the fact it's maybe an older study and maybe not the same type of material, but comparing Burch versus sling.

Q. And why is it that you wanted to cite papers pertaining to a comparison between the Burch procedure and sling procedures?

A. I was trying to establish the fact that there are different ways to treat this condition and to educate myself and certainly have it reflected in my reports regarding the pros and cons of each approach.

- - -

(Deposition Exhibit No. Walmsley-7, Article entitled "Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence," by Albo, et

al., was marked for identification.)

- - -

BY MR. TOMASELLI:

Q. I'm going to mark as Deposition Exhibit Number 7 the paper by Albo and colleagues in the New England Journal of Medicine from 2007.

Do you see that?

A. I do.

Q. Are you familiar with this paper?

A. Vaguely. I remember reading this paper.

Q. Because you said you were interested in comparisons related to the Burch procedure and autologous rectus fascia, that's the reason I gave you this paper. Okay?

A. Correct.

Q. All right.

A. Yeah.

Q. And, indeed, this is a large randomized trial comparing the Burch

procedure to autologous rectal fascia?

A. Correct.

Q. And if we turn, for example, to Table 2, and all the information below Table 2, do you see where it talks about a variety of adverse events?

A. I see the table, yes.

Q. And, indeed, that table does talk about a variety of adverse events that occurred within the trial?

A. Yes.

Q. All right. And surgeons like yourself looking at medical literature can find this as one place of information to see what types of adverse events other surgeons are encountering during procedures for stress urinary incontinence?

A. Fair.

Q. Coming back to Deposition Exhibit Number 6, the Enzelsberger paper, can you tell me when you have that?

A. I have it.

Q. Can you turn to page 254,

which has Table 3 in the upper right-hand corner?

A. Yes.

Q. We talked previously about the fact that patients can have urgency symptoms and urge incontinence post or after stress urinary incontinence surgery; is that right?

A. Correct.

Q. And in Table 3, for example, it talks about 8 percent of the patients following Burch and 16 percent of the patients following sling procedure had urgency or urge incontinence.

Do you see that?

A. I do.

Q. Is that consistent with your experience?

A. You know, my exposure to Burches are a little limited. Certainly with regards to the sling procedure, I have a slightly lower experience, but that's fairly representative.

Q. Okay. The next paper in

your report I couldn't find, so we'll go to the next one, which is by Guerrero.

- - -

(Deposition Exhibit No. Walmsley-8, Article entitled "A randomised controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up" by Guerrero, et al., was marked for identification.)

- - -

BY MR. TOMASELLI:

Q. And I promise that I'm not going to do this with all of them. All right. Withdrawn.

Dr. Walmsley, I'm handing you what I've marked as Deposition Exhibit Number 8 --

A. Yep.

Q. -- which is a paper by Guerrero and others which you cited in

your expert report; is that right?

A. Yep. Yes.

Q. And can you describe for me, if you can, the reason, if you recall, that you cited this paper in your expert report?

A. Primarily to have a fairly large core of patients, I mean, it's a group of almost 100 -- 165 women who received autologous fascial slings, the intention being to get an idea of success rates and things of that nature.

Q. And when you talk about the type of sling that they received in this Deposition Exhibit Number 8, that's the type of sling that you referred to in general opinion number 2?

A. Yes. Although the techniques are -- there's a modification on the technique that I don't currently employ called sling on a string.

Q. Okay. And if we turn over to page 1266, do you see that in the pros portion of 1266 on the right-hand column,

there's a paragraph that starts, "Table 3 shows"?

A. You're on page 1266?

Q. 1266.

A. Yes.

Q. Do you see there's a paragraph there that starts "Table 3 shows"?

A. I see that.

Q. Okay. It states, "As expected, the baseline incidence is 100% in both groups."

They're speaking of stress urinary incontinence; is that right?

A. Yes, I see that.

Q. And the stress urinary incontinence decreases to between 10 and 21 percent at three months.

Do you see that?

A. I see that.

Q. So would you interpret that to mean that of all these patients that are undergoing this stress urinary incontinence surgery, between 10 and

21 percent, they continued to have some stress urinary incontinence surgery -- stress urinary incontinence after their surgery?

A. Yeah. I mean, in this cohort of British women at this clinic, that's the case.

Q. Okay. And then if we go down, continuing in the paragraph, it states that the -- the leakage, that is, the stress urinary incontinence in the women, continues to rise over time?

A. Correct.

Q. And by the long-term follow-up, the incidence of leakage is at best 38 to 43 percent, but could be as high as 71 percent.

Do you see that?

A. I do see that.

Q. Okay. If you can turn over a couple of pages to Table 6 at the bottom of page 1268 and tell me when you're there.

A. I'm here.

Q. Do you see that there's a table talking about pain?
A. Yes.
Q. All right. And there's a line or row that talks about how many people had pain even three months after operation; is that right?
A. Yes.
Q. And do you see that in these two groups, 51 percent in one group and 67 percent in another group continue to have pain three months after surgery?
A. I see that.
Q. All right. And again, in terms of above Table 6, up into Table 5 on the same page, there's a description of complications. Right?
A. Yes.
Q. And surgeons like yourself reading these articles can look at complications and see what other surgeons have encountered with respect to stress urinary incontinence procedures?
A. They can use this as a

resource, yes.

Q. The -- if you look back to your report, Doctor, where we were moving down the articles, do you see that the next article that you reference in your report is by Welk?

A. Yes.

Q. And tell me if I'm wrong, but it looks like the remainder of the articles that you talk about in your report deal more with complications following midurethral sling placement. Is that fair?

A. Yeah, that's correct.

Q. Are there any other articles that you cite --

A. May I just --

Q. Yeah, yeah, sure.

A. The Petri and Klosterhalfen are two that really don't, but you're talking about Anger, from Anger on is where those are really more of the complication-based references. Is that what you said?

Q. Even Petri, you know, the title is "Complications of synthetic slings"?

A. Yeah. It's just that -- yeah, I guess Klosterhalfen is not specifically a complication one, per se, but the others are. Yes.

Q. Okay. I guess Moalli actually relates to the properties of mesh as well?

A. Correct, yeah.

Q. I guess my question is this: Other than the papers that we talked about and the one that I couldn't get on porcine dermal sling, are there other papers that are in the top of your head that you're relying on for your opinions in this case?

A. In this case, what's stated in the report is what's reflective of my opinions in the report.

MR. TOMASELLI: Okay. I will tell you what, can we go off the record for just a minute.

MR. ORENT: Sure.

MR. TOMASELLI: I'm going to try to finish real quick. Okay? So if you've just got 2 or 3 minutes, I'm going to look at my stuff.

- - -

(A recess was taken from 1:52 p.m. to 1:58 p.m.)

- - -

BY MR. TOMASELLI:

Q. Dr. Walmsley, are you ready?

A. Yes, sir.

Q. Dr. Walmsley, we took a quick break, and are you ready to proceed?

A. I am.

Q. Great. I'm handing you what I've marked as Deposition Exhibit Number 9.

- - -

(Deposition Exhibit No. Walmsley-9, AUA Position Statement on the Use of Vaginal mesh for the Surgical Treatment of Stress

Urinary Incontinence (SUI), was marked for identification.)

- - -

BY MR. TOMASELLI:

Q. And this is a "Position Statement on the Use of...Mesh for the Treatment of Stress Urinary Incontinence" from the American Urological Association.

Do you see that?

A. I do.

Q. And you told me that you're a member of the AUA?

A. I am.

Q. Okay. Have you seen this before?

A. I have.

Q. And do you agree with the position statement of the American Urological Association?

MR. ORENT: Objection.

THE WITNESS: In part I agree, yes.

BY MR. TOMASELLI:

Q. Okay. Do you agree that

with -- withdrawn.

Do you agree with the statements -- statement that -- withdrawn.

Do you agree with the association statement that "Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female stress urinary incontinence, with minimal morbidity compared with alternative surgeries"?

MR. ORENT: Objection.

THE WITNESS: I do agree with that.

BY MR. TOMASELLI:

Q. Do you agree with the next sentence that "Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction"?

MR. ORENT: Objection.

THE WITNESS: I do.

BY MR. TOMASELLI:

Q. Do you agree that "Mesh-related complications can occur following polypropylene sling placement, but the rate of...complications is acceptably low"?

MR. ORENT: Objection.

THE WITNESS: Not exactly.

BY MR. TOMASELLI:

Q. But it is true that today you continue to use polypropylene midurethral slings for the treatment of stress urinary incontinence?

A. In the context of proper informed consent, I do, yes.

Q. Okay. Do you agree that "it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well"?

A. I think, once again, from a quantitative statement, yes. From a qualitative standpoint, there needs to be a proper discussion with patients.

Q. Have you ever written the American Urological Association and noted any disagreement with this position statement?

A. I never write to the AUA.

Q. Did you ever provide any comments to this position statement?

A. I talked to my colleagues about it.

Q. Okay. And did you talk to them about what we just talked about?

A. Yes, yeah.

Q. Do your colleagues, your partners that you practice with, do they also continue to place polypropylene midurethral slings for the treatment of stress urinary incontinence?

MR. ORENT: Objection.

THE WITNESS: Not all of them.

BY MR. TOMASELLI:

Q. Some of them do?

MR. ORENT: Objection.

THE WITNESS: Some do.

BY MR. TOMASELLI:

Q. In terms of some of the studies that we were just looking at, we looked at a number of randomized clinical trials.

Do you remember that?

A. We did look at some, yes.

Q. And you're familiar with what a randomized clinical trial is?

A. Yes.

Q. Would you agree that it's the highest level of evidence to compare interventions in a particular indication?

A. I think it's very strong.

Q. Would you also agree that systematic analyses of multiple randomized trials are also a strong way to look at data and compare interventions?

A. I think they can be helpful, yes.

Q. In your practice, do you rely on randomized clinical trials and systematic reviews of randomized clinical

trials to help inform your opinions and judgments in your practice?

MR. ORENT: Objection.

THE WITNESS: Assuming that I hold the evidence in high regard, I do, yes.

BY MR. TOMASELLI:

Q. Looking at the papers -- withdrawn.

I think what you just said is as long as you can read the paper and are comfortable with the methods in the randomized trial that's being done, you would be comfortable taking those results and putting them into the calculus, so to speak, of your practice?

MR. ORENT: Objection.

THE WITNESS: I mean, I think the construct of those types of trials, randomized control trials, systematic reviews, can be helpful, assuming that the endpoints that are looked at are relevant to me in my practice. That's my point, yeah.

MR. TOMASELLI: I will pass the witness at this point. And thank you for your time.

THE WITNESS: Thank you.

- - -

EXAMINATION

- - -

BY MR. ORENT:

Q. Doctor, just a few questions on Exhibit Number 9.

A. Yes.

Q. Would you agree with me, Doctor, that this is not a scientific statement?

MR. TOMASELLI: Objection, leading.

THE WITNESS: This is a position statement, that's correct.

BY MR. ORENT:

Q. And a position statement is an advocacy piece. Correct?

MR. TOMASELLI: Objection to form, leading.

THE WITNESS: Yeah, to some

degree that's correct.

BY MR. ORENT:

Q. And, Doctor, would you agree that as a practitioner, you would not blindly rely upon a position statement like this for your choices in medical care and treatment of your patients?

MR. TOMASELLI: Object to form, leading.

THE WITNESS: This has no impact on how I use mesh or did not influence me in any way for my presence or lack of presence to use mesh.

BY MR. ORENT:

Q. And a doctor in your situation, your position, a board certified urologist who performs stress urinary incontinence procedures, would a urologist like yourself rely upon a position statement like this for the decision to use a device?

MR. TOMASELLI: Object to form, asked and answered.

THE WITNESS: No.
BY MR. ORENT:
Q. Now, Doctor, this position statement by AUA doesn't -- on the face of it excludes mini slings, single-incision mini slings like TVT-S; isn't that right?
MR. TOMASELLI: Object to form, leading.
THE WITNESS: Well, there's no comment here regarding mini slings. And for the record, I mean, this is a statement that was published in 2011.
BY MR. ORENT:
Q. Let me just point out one thing. "Additionally, both the Society of Urodynamics" --
A. Uh-huh.
Q. Do you see where I am?
A. Yes.
Q. -- "Female Pelvic Medicine and Urogenital Reconstruction (SUFU) and the AUA support the use of multi-incision monofilament midurethral slings for the

treatment of SUI in properly selected patients who are appropriately counseled regarding this this" -- there's a typo there -- "surgical procedure by surgeons who are trained in the placement of such devices, as well as the recognition and management of potential complications associated with their use."

Did I read that correctly, Doctor?

A. You did.

Q. Now, Doctor, that specifically references multi-incision slings; is that right?

A. Correct.

Q. And the TVT-S that you're opining about today is not a multi-incision sling; is that correct?

A. That's correct.

Q. And so by its very terms, this statement does not apply to the product that you are discussing here today. Is that true?

MR. TOMASELLI: Object to

leading.

THE WITNESS: Based on that statement, yes.

BY MR. ORENT:

Q. Okay. Now, Doctor, you would agree with me that even for multi-incision devices, this lumps them all together?

A. It does.

Q. And would you agree, Doctor, that not all multi-incision polypropylene mesh slings are created equal?

MR. TOMASELLI: Object to form, leading.

THE WITNESS: This is true.

BY MR. ORENT:

Q. And an example of that would be Mentor's ObTape device is made of polypropylene. Correct?

A. Yes.

Q. And it was a multi-incision full-length sling. Correct?

A. Correct.

Q. It was a midurethral

transobturator sling. Correct?

A. Yes.

Q. And so theoretically, that would be included under AUA's position statement. Correct?

MR. TOMASELLI: Object to form, leading.

THE WITNESS: That's correct.

BY MR. ORENT:

Q. And, Doctor, would you agree with me that no reputable doctor today would support the safety and efficacy of the Mentor ObTape?

MR. TOMASELLI: Leading.

THE WITNESS: That's correct.

BY MR. ORENT:

Q. Similarly, each device at issue -- excuse me, each device has different amounts of data associated with it. Correct?

A. True.

Q. Different devices have

different pore sizes. Correct?

A. Yes.

Q. And they have different stiffness and other physical properties. Correct?

MR. TOMASELLI: Object to form, leading.

THE WITNESS: Yes.

BY MR. ORENT:

Q. And, Doctor, in your professional opinion, do you believe that a device needs to be evaluated on its own merits as opposed to lumped together?

MR. TOMASELLI: Object to form, leading.

THE WITNESS: Certainly, yes.

BY MR. ORENT:

Q. And, Doctor, with -- if you look at the last big paragraph, "Multiple case series and randomized controlled trials attest to the efficacy of synthetic polypropylene mesh slings at 5-10 years," Doctor, are you, as you sit

here today, aware of any 10-year data on the TVT-S?

A. I'm not.

Q. And, Doctor, are you aware of any 5-year data on the TVT-S?

A. I'm not.

Q. And you performed a literature search for each of those items, did you not?

A. I did.

MR. ORENT: Thank you very much, Doctor. I have no further questions.

- - -

EXAMINATION

- - -

BY MR. TOMASELLI:

Q. Doctor, did you perform a thorough literature search to see if there was any 5-year randomized data with respect to the TVT SECUR?

A. I couldn't find any in my research, unless I missed something.

MR. TOMASELLI: I think

we're done here.

MR. ORENT: Excellent.

(Witness excused.)

(Deposition concluded at approximately 2:11 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, KONSTANTIN WALMSLEY, MD, have the opportunity to read and sign the deposition transcript.

_____

ANN MARIE MITCHELL, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 131, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

KONSTANTIN WALMSLEY, MD DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

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